premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.

§ 892.1710 Mammographic x-ray system.

(a) *Identification.* A mammographic x-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1715 Full-field digital mammography system.

(a) *Identification.* A full-field digital mammography system is a device intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II (special controls). The special control for the device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Full-Field Digital Mammography System.'' *See* § 892.1(e) for the availability of this guidance document.

§ 892.1720 Mobile x-ray system.

(a) *Identification.* A mobile x-ray system is a transportable device system intended to be used to generate and control x-ray for diagnostic procedures. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1730 Photofluorographic x-ray system.

(a) *Identification.* A photofluorographic x-ray system is a device that includes a fluoroscopic x-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1740 Tomographic x-ray system.

(a) *Identification.* A tomographic x-ray system is an x-ray device intended to be used to produce radiologic images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1750 Computed tomography x-ray system.

(a) *Identification.* A computed tomography x-ray system is a diagnostic x-ray system intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1760 Diagnostic x-ray tube housing assembly.

(a) *Identification.* A diagnostic x-ray tube housing assembly is an x-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9.